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Counsel for Plaintiff Intra-Cellular Therapies, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Intra-Cellular Therapies, Inc., *Plaintiff*, v. Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd., *Defendants*.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Intra-Cellular Therapies, Inc. ("Intra-Cellular Therapies," "ITCI," or "Plaintiff"), by its attorneys, files this Complaint for patent infringement against Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, "DRL") and hereby alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, that arises out of DRL's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of CAPLYTA® (lumateperone) capsules, 10.5 mg, 21 mg, and 42 mg, prior to the expiration of U.S. Patent Nos. 8,648,077 ("the '077 patent"), 9,168,258 ("the '258 patent"), 9,199,995 ("the '995 patent"), 9,616,061 ("the '061 patent"), 9,956,227 ("the '227 patent"), 10,117,867 ("the '867 patent"), 10,464,938 ("the '938 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), RE48,825 ("the RE '825 patent"), and RE48,839 ("the RE '839 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

2. DRL notified Plaintiff by letter dated February 16, 2024 ("DRL's Notice Letter") that it had submitted to the FDA ANDA No. 219229 ("DRL's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, ("DRL's ANDA Product") prior to the expiration of the Patents-in-Suit.

The Parties

3. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

4. Plaintiff Intra-Cellular Therapies ("ITCI") is a corporation organized and existing under the laws of Delaware and having a place of business at 430 East 29th Street, Suite 900, New York, NY 10016. ITCI is the holder of New Drug Application ("NDA") No. 209500 for the manufacture and sale of lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, which have been approved by the FDA.

5. Upon information and belief, Defendant Dr. Reddy's Laboratories Inc. is a corporation organized and existing under the laws of New Jersey and having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

6. Upon information and belief, Defendant Dr. Reddy's Laboratories Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India, 500034.

7. Upon information and belief, Dr. Reddy's Laboratories Inc. is the U.S. Regulatory Agent for Dr. Reddy's Laboratories Ltd.

8. Upon information and belief, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc. acted in concert to prepare and submit DRL's ANDA to the FDA. Upon information and belief, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc. know and intend that upon approval of DRL's ANDA, Dr. Reddy's Laboratories Ltd. will manufacture DRL's ANDA Product, and Dr. Reddy's Laboratories Inc. will directly or indirectly market, sell, and distribute DRL's ANDA Product throughout the United States, including in New Jersey.

9. Upon information and belief, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to DRL's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Dr. Reddy's

Laboratories Inc. participated in, assisted, and cooperated with Dr. Reddy's Laboratories Ltd. in the acts complained of herein.

10. Upon information and belief, following any FDA approval of DRL's ANDA, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc. will act in concert to distribute and sell DRL's ANDA Product throughout the United States, including within New Jersey.

Jurisdiction

11. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

12. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

13. This Court has personal jurisdiction over each of Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc.

14. Dr. Reddy's Laboratories Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Dr. Reddy's Laboratories Ltd., itself and through its subsidiary Dr. Reddy's Laboratories Inc., has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Dr. Reddy's Laboratories Ltd., itself and through its subsidiary Dr. Reddy's Laboratories Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey and therefore transacts business within the State of New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Dr. Reddy's Laboratories Ltd. is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Dr. Reddy's Laboratories Inc. and therefore the activities of Dr. Reddy's Laboratories Inc. in this jurisdiction are attributed to Dr. Reddy's Laboratories Ltd.

15. Dr. Reddy's Laboratories Inc. is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Dr. Reddy's Laboratories Inc. is a corporation organized and existing under the laws of the State of New Jersey, has a principal place of business in the State of New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. In addition, upon information and belief, Dr. Reddy's Laboratories Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey and therefore transacts business within the State of New Jersey related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

16. DRL has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

17. Upon information and belief, DRL, with knowledge of the Hatch-Waxman Act process, directed DRL's Notice Letter to Plaintiff. Upon information and belief, DRL knew when it did so that it was triggering the forty-five-day period for Plaintiff to bring an action for patent infringement under the Hatch-Waxman Act. DRL has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending DRL's Notice Letter to Plaintiff it would be sued for patent infringement in New Jersey, where Dr. Reddy's Laboratories Inc. is located and incorporated.

18. Upon information and belief, if DRL's ANDA is approved, DRL will directly or indirectly manufacture, market, sell, and/or distribute DRL's ANDA Product within the United States, including in New Jersey, consistent with DRL's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, DRL regularly does business in New Jersey, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. Upon information and belief, DRL's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, DRL's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-in-Suit in the event that DRL's ANDA Product is approved before the patents expire.

19. Upon information and belief, DRL derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which are manufactured by DRL and/or Dr. Reddy's Laboratories Inc. or Dr. Reddy's Laboratories Ltd. Upon information and belief, various products for which Dr. Reddy's Laboratories Ltd. or Dr. Reddy's Laboratories Inc. is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

Venue

20. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

21. Venue is proper in this district as to Dr. Reddy's Laboratories Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Dr. Reddy's Laboratories Inc. is a corporation

organized and existing under the laws of the State of New Jersey, has a principal place of business in the State of New Jersey, and is subject to personal jurisdiction in this judicial district.

22. Venue is proper in this district as to Dr. Reddy's Laboratories Ltd. pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) because, *inter alia*, Dr. Reddy's Laboratories Ltd. is a company organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

Factual Background

23. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

24. CAPLYTA®, which contains lumateperone, is approved for the treatment of schizophrenia in adults, as well as depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate.

25. In DRL's Notice Letter, DRL stated that the subject of DRL's ANDA is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. In DRL's Notice Letter, DRL stated that DRL's ANDA was submitted under 21 U.S.C. § 355(j)(1) & (2)(a) and contended that DRL's ANDA contains bioavailability and/or bioequivalence studies for DRL's ANDA Product. Upon information and belief, DRL's ANDA Product is a generic version of CAPLYTA®.

26. In DRL's Notice Letter, DRL stated that it had submitted Paragraph IV certifications to the FDA alleging that the Patents-in-Suit are invalid, unenforceable, and/or not infringed, and that DRL is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit.

27. The purpose of DRL's submission of DRL's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act (the "FDCA") to engage in the commercial

manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit.

28. Upon information and belief, DRL's ANDA Product is not publicly available, nor is ANDA No. 219229 accessible to the public.

29. In DRL's Notice Letter, DRL included an Offer of Confidential Access to a redacted version of DRL's ANDA, and DRL's offer was subject to various unreasonably restrictive conditions.

30. In an exchange of correspondence, counsel for Plaintiff and counsel for DRL discussed the terms of DRL's Offer of Confidential Access. The parties did not agree on terms under which Plaintiff could review, among other things, DRL's unredacted ANDA, any Drug Master File referred to therein, or all relevant characterization data. DRL further refused to produce samples of DRL's ANDA Product and other internal documents and material relevant to infringement.

31. This action is being commenced within 45 days from the date Plaintiff received DRL's Notice Letter.

Count I—Infringement of the RE '839 Patent

32. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

33. The RE '839 patent, entitled "Methods and Compositions for Sleep Disorders and Other Disorders" (attached as Exhibit A), was duly and legally issued on December 7, 2021.

34. The inventors named on the RE '839 patent are Sharon Mates, Allen Fienberg, and Lawrence Wennogle.

35. Plaintiff is the owner and assignee of the RE '839 patent.

36. CAPLYTA® is covered by one or more claims of the RE '839 patent, which has been listed in connection with CAPLYTA® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

37. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the RE '839 patent.

38. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the RE '839 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the RE '839 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

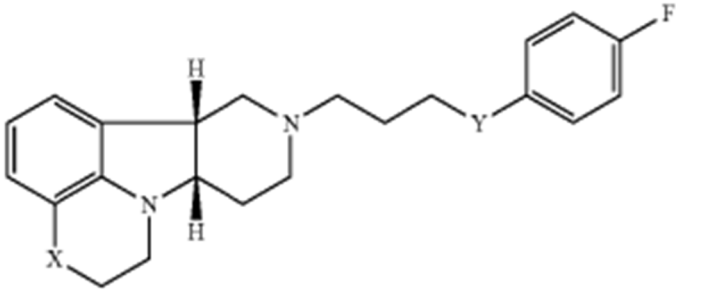
39. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

40. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling for that product would infringe one or more claims of the RE '839 patent.

41. As an example, claim 1 of the RE '839 patent recites:

> A method for the treatment of one or more 5-HT$_{2A}$-related disorders, comprising administering to a patient in need thereof a Compound of Formula I:

Formula I



wherein X is O, —NH or —N(CH_3); and Y is —O— or —C(O) —, in free or pharmaceutically acceptable salt form, in a dose which selectively blocks the 5-HT_{2A} receptor.

42. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed label would involve treating one or more 5-HT_{2A}-related disorders, including by administering to the patient in need thereof a free or pharmaceutically acceptable salt form of a Formula I compound (which includes lumateperone) in a dose which selectively blocks the 5-HT_{2A} receptor, as recited in claim 1.

43. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed product labeling would infringe one or more claims of the RE '839 patent, literally or under the doctrine of equivalents.

44. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the RE '839 patent was an act of infringement of the RE '839 patent under 35 U.S.C. § 271(e)(2)(A).

45. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

46. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the RE '839 patent.

47. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the RE '839 patent.

48. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the RE '839 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the RE '839 patent and specific intent to infringe that patent.

49. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the RE '839 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the RE '839 patent immediately and imminently upon approval of DRL's ANDA.

50. Notwithstanding DRL's knowledge of the claims of the RE '839 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the RE '839 patent.

51. The foregoing actions by DRL constitute and/or will constitute infringement of the RE '839 patent; active inducement of infringement of the RE '839 patent; and/or contribution to the infringement by others of the RE '839 patent.

52. Upon information and belief, DRL has acted with full knowledge of the RE '839 patent and without a reasonable basis for believing that it would not be liable for infringement of the RE '839 patent; active inducement of infringement of the RE '839 patent; and/or contribution to the infringement by others of the RE '839 patent.

53. Plaintiff will be substantially and irreparably damaged by infringement of the RE '839 patent.

54. Unless DRL is enjoined from infringing the RE '839 patent, actively inducing infringement of the RE '839 patent, and contributing to the infringement by others of the RE '839 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count II—Declaratory Judgment of Infringement of the RE '839 Patent

55. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

56. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the RE '839 patent, and/or the validity of the RE '839 patent.

57. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the RE '839 patent, will infringe, induce infringement of, and contribute to the infringement by others of the RE '839 patent, and that the claims of the RE '839 patent are not invalid.

Count III—Infringement of the '258 Patent

58. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

59. The ’258 patent, entitled “Methods and Compositions for Sleep Disorders and Other Disorders” (attached as Exhibit B), was duly and legally issued on October 27, 2015.

60. The inventors named on the ’258 patent are Sharon Mates, Allen Fienberg, and Lawrence P. Wennogle.

61. Plaintiff is the owner and assignee of the ’258 patent.

62. CAPLYTA® is covered by one or more claims of the ’258 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

63. In DRL’s Notice Letter, DRL notified Plaintiff of the submission of DRL’s ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL’s ANDA Product prior to the expiration of the Patents-in-Suit, including the ’258 patent.

64. In DRL’s Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the ’258 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the ’258 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL’s ANDA Product.

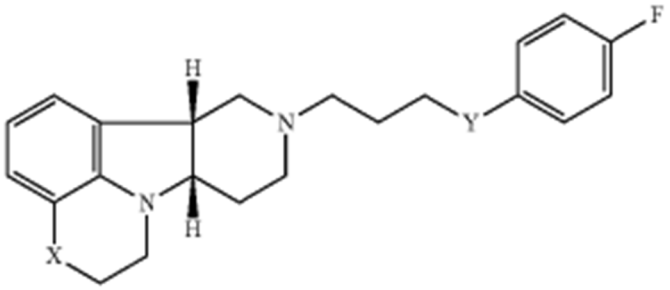
65. According to DRL’s Notice Letter, DRL’s ANDA Product contains lumateperone.

66. Upon information and belief, DRL’s ANDA Product and the use of DRL’s ANDA Product are covered by one or more claims of the ’258 patent, either literally or under the doctrine of equivalents.

67. As an example, claim 1 of the ’258 patent recites:

> A pharmaceutical composition in oral unit dose form comprising an amount of 10 mg or less of a Compound of Formula I:

Formula I



wherein X is O, —NH or —N(CH_3); and Y is —O— or —C(O) —, in free or pharmaceutically acceptable salt form, in combination or association with a pharmaceutically acceptable diluent or carrier, provided that in the case of a salt, the weight is calculated as the free base, where the amount of the Compound of Formula I:

a) is sufficient to block the 5-HT_{2A} receptor; and

b) either does not block, or minimally blocks the dopamine D2 receptor.

68. Upon information and belief, DRL's ANDA Product contains a pharmaceutical composition in oral unit dose form containing an amount of 10 mg or less (calculated as the free base) of a Formula I compound (lumateperone) in pharmaceutically acceptable salt form in combination or association with a pharmaceutically acceptable diluent or carrier and in an amount that is sufficient to block the 5-HT_{2A} receptor and that does not block, or minimally blocks, the dopamine D2 receptor, as recited in claim 1.

69. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '258 patent, literally or under the doctrine of equivalents.

70. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's

ANDA Product before the expiration of the '258 patent was an act of infringement of the '258 patent under 35 U.S.C. § 271(e)(2)(A).

71. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

72. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '258 patent.

73. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '258 patent.

74. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '258 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '258 patent and specific intent to infringe that patent.

75. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '258 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '258 patent immediately and imminently upon approval of DRL's ANDA.

76. Notwithstanding DRL's knowledge of the claims of the '258 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's

ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '258 patent.

77. The foregoing actions by DRL constitute and/or will constitute infringement of the '258 patent; active inducement of infringement of the '258 patent; and/or contribution to the infringement by others of the '258 patent.

78. Upon information and belief, DRL has acted with full knowledge of the '258 patent and without a reasonable basis for believing that it would not be liable for infringement of the '258 patent; active inducement of infringement of the '258 patent; and/or contribution to the infringement by others of the '258 patent.

79. Plaintiff will be substantially and irreparably damaged by infringement of the '258 patent.

80. Unless DRL is enjoined from infringing the '258 patent, actively inducing infringement of the '258 patent, and contributing to the infringement by others of the '258 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count IV—Declaratory Judgment of Infringement of the '258 Patent

81. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

82. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '258 patent, and/or the validity of the '258 patent.

83. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '258 patent, will infringe, induce

infringement of, and contribute to the infringement by others of the ’258 patent, and that the claims of the ’258 patent are not invalid.

Count V—Infringement of the ’061 Patent

84. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

85. The ’061 patent, entitled “Methods and Compositions for Sleep Disorders and Other Disorders” (attached as Exhibit C), was duly and legally issued on April 11, 2017.

86. The inventors named on the ’061 patent are Sharon Mates, Allen Fienberg, and Lawrence Wennogle.

87. Plaintiff is the owner and assignee of the ’061 patent.

88. CAPLYTA® is covered by one or more claims of the ’061 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

89. In DRL’s Notice Letter, DRL notified Plaintiff of the submission of DRL’s ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL’s ANDA Product prior to the expiration of the Patents-in-Suit, including the ’061 patent.

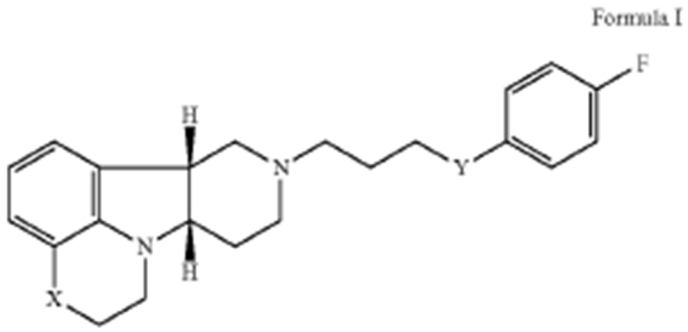
90. In DRL’s Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the ’061 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the ’061 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL’s ANDA Product.

91. According to DRL’s Notice Letter, DRL’s ANDA Product contains lumateperone.

92. Upon information and belief, DRL’s ANDA Product and the use of DRL’s ANDA Product are covered by one or more claims of the ’061 patent, either literally or under the doctrine of equivalents.

93. As an example, claim 1 of the '061 patent recites:

> A pharmaceutical composition in oral unit dose form comprising an amount of from 0.1-20 mg of a Compound of Formula I:



> wherein X is —N(CH_3); and Y is —C(O)—, in free or pharmaceutically acceptable salt form, in combination or association with a pharmaceutically acceptable diluent or carrier, provided that in the case of a salt, the weight is calculated as the free base.

94. Upon information and belief, DRL's ANDA Product contains a pharmaceutical composition in oral unit dose form containing an amount of from 0.1-20 mg (calculated as the free base) of a Formula I compound (lumateperone) in pharmaceutically acceptable salt form in combination or association with a pharmaceutically acceptable diluent or carrier, as recited in claim 1.

95. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '061 patent, literally or under the doctrine of equivalents.

96. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '061 patent was an act of infringement of the '061 patent under 35 U.S.C. § 271(e)(2)(A).

97. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

98. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '061 patent.

99. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '061 patent.

100. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '061 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '061 patent and specific intent to infringe that patent.

101. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '061 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '061 patent immediately and imminently upon approval of DRL's ANDA.

102. Notwithstanding DRL's knowledge of the claims of the '061 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '061 patent.

103. The foregoing actions by DRL constitute and/or will constitute infringement of the '061 patent; active inducement of infringement of the '061 patent; and/or contribution to the infringement by others of the '061 patent.

104. Upon information and belief, DRL has acted with full knowledge of the '061 patent and without a reasonable basis for believing that it would not be liable for infringement of the '061 patent; active inducement of infringement of the '061 patent; and/or contribution to the infringement by others of the '061 patent.

105. Plaintiff will be substantially and irreparably damaged by infringement of the '061 patent.

106. Unless DRL is enjoined from infringing the '061 patent, actively inducing infringement of the '061 patent, and contributing to the infringement by others of the '061 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count VI—Declaratory Judgment of Infringement of the '061 Patent

107. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

108. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '061 patent, and/or the validity of the '061 patent.

109. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '061 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '061 patent, and that the claims of the '061 patent are not invalid.

Count VII—Infringement of the '867 Patent

110. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

111. The '867 patent, entitled "Methods and Compositions for Sleep Disorders and Other Disorders" (attached as Exhibit D), was duly and legally issued on November 6, 2018.

112. The inventors named on the '867 patent are Sharon Mates, Allen Fienberg, and Lawrence P. Wennogle.

113. Plaintiff is the owner and assignee of the '867 patent.

114. CAPLYTA® is covered by one or more claims of the '867 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

115. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '867 patent.

116. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '867 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '867 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

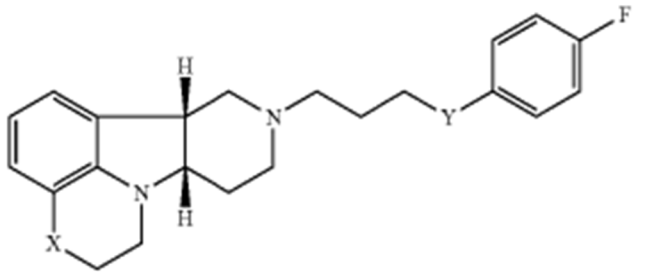
117. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

118. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling for that product would infringe one or more claims of the '867 patent.

119. As an example, claim 1 of the '867 patent recites:

A method for the treatment of bipolar depression, comprising administering to a patient in need thereof a Compound of Formula I:

Formula I



wherein X is O, —NH or —N(CH_3); and Y is —O— or —C(O) —, in free or pharmaceutically acceptable salt form.

120. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed label would involve treating bipolar depression, including by administering to the patient in need thereof a free or pharmaceutically acceptable salt form of a Formula I compound, as recited in claim 1.

121. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '867 patent, literally or under the doctrine of equivalents.

122. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '867 patent was an act of infringement of the '867 patent under 35 U.S.C. § 271(e)(2)(A).

123. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

124. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '867 patent.

125. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '867 patent.

126. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '867 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '867 patent and specific intent to infringe that patent.

127. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '867 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '867 patent immediately and imminently upon approval of DRL's ANDA.

128. Notwithstanding DRL's knowledge of the claims of the '867 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '867 patent.

129. The foregoing actions by DRL constitute and/or will constitute infringement of the '867 patent; active inducement of infringement of the '867 patent; and/or contribution to the infringement by others of the '867 patent.

130. Upon information and belief, DRL has acted with full knowledge of the '867 patent and without a reasonable basis for believing that it would not be liable for infringement of the '867 patent; active inducement of infringement of the '867 patent; and/or contribution to the infringement by others of the '867 patent.

131. Plaintiff will be substantially and irreparably damaged by infringement of the '867 patent.

132. Unless DRL is enjoined from infringing the '867 patent, actively inducing infringement of the '867 patent, and contributing to the infringement by others of the '867 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count VIII—Declaratory Judgment of Infringement of the '867 Patent

133. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

134. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '867 patent, and/or the validity of the '867 patent.

135. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '867 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '867 patent, and that the claims of the '867 patent are not invalid.

Count IX—Infringement of the '077 Patent

136. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

137. The '077 patent, entitled "4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone

Toluenesulfonic Acid Addition Salt and Salt Crystals" (attached as Exhibit E), was duly and legally issued on February 11, 2014.

138. The inventors named on the '077 patent are John Tomesch and Lawrence P. Wennogle.

139. Plaintiff is the owner and assignee of the '077 patent.

140. CAPLYTA® is covered by one or more claims of the '077 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

141. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '077 patent.

142. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '077 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '077 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

143. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

144. Upon information and belief, DRL's ANDA Product and the use of DRL's ANDA Product are covered by one or more claims of the '077 patent, either literally or under the doctrine of equivalents.

145. As an example, claim 1 of the '077 patent recites:

> A toluenesulfonic acid addition salt crystal of 4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-

> fluorophenyl)-1-butanone, wherein said salt crystal exhibits an X-ray powder diffraction pattern comprising at least two peaks having 2-theta values selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°, wherein the X-ray powder diffraction data is collected on a diffractometer operating with a copper anode with a nickel filter.

146. Upon information and belief, DRL's ANDA Product contains a crystalline form of the compound recited in claim 1.

147. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '077 patent, literally or under the doctrine of equivalents.

148. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '077 patent was an act of infringement of the '077 patent under 35 U.S.C. § 271(e)(2)(A).

149. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

150. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '077 patent.

151. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '077 patent.

152. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '077 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '077 patent and specific intent to infringe that patent.

153. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '077 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '077 patent immediately and imminently upon approval of DRL's ANDA.

154. Notwithstanding DRL's knowledge of the claims of the '077 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '077 patent.

155. The foregoing actions by DRL constitute and/or will constitute infringement of the '077 patent; active inducement of infringement of the '077 patent; and/or contribution to the infringement by others of the '077 patent.

156. Upon information and belief, DRL has acted with full knowledge of the '077 patent and without a reasonable basis for believing that it would not be liable for infringement of the '077 patent; active inducement of infringement of the '077 patent; and/or contribution to the infringement by others of the '077 patent.

157. Plaintiff will be substantially and irreparably damaged by infringement of the '077 patent.

158. Unless DRL is enjoined from infringing the '077 patent, actively inducing infringement of the '077 patent, and contributing to the infringement by others of the '077 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count X—Declaratory Judgment of Infringement of the '077 Patent

159. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

160. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '077 patent, and/or the validity of the '077 patent.

161. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '077 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '077 patent, and that the claims of the '077 patent are not invalid.

Count XI—Infringement of the '995 Patent

162. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

163. The '995 patent, entitled "4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals" (attached as Exhibit F), was duly and legally issued on December 1, 2015.

164. The inventors named on the '995 patent are John Tomesch and Lawrence P. Wennogle.

165. Plaintiff is the owner and assignee of the '995 patent.

166. CAPLYTA® is covered by one or more claims of the '995 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

167. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '995 patent.

168. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '995 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '995 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

169. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

170. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling for that product would infringe one or more claims of the '995 patent.

171. As an example, claim 2 of the '995 patent recites:

> A method for modulating 5-hydroxytryptamine 2A receptor activity in a patient, comprising administering to a patient in need thereof an effective amount of 4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′: 4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone toluene sulfonic acid salt crystal, wherein said salt crystal exhibits an X-ray powder diffraction pattern comprising at least two peaks having 2-theta values selected from the group consisting of 5.68°, 12.11°, 16.04°,

17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°, wherein the X-ray powder diffraction data is collected on a diffractometer operating with a copper anode with a nickel filter.

172. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed label would involve modulating 5-hydroxytryptamine 2A receptor activity in a patient, including by administering to the patient in need thereof an effective amount of the salt crystal recited in claim 2.

173. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '995 patent, literally or under the doctrine of equivalents.

174. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '995 patent was an act of infringement of the '995 patent under 35 U.S.C. § 271(e)(2)(A).

175. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

176. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '995 patent.

177. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '995 patent.

178. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '995 patent when DRL's ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '995 patent and specific intent to infringe that patent.

179. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '995 patent immediately and imminently upon approval of DRL's ANDA.

180. Notwithstanding DRL's knowledge of the claims of the '995 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '995 patent.

181. The foregoing actions by DRL constitute and/or will constitute infringement of the '995 patent; active inducement of infringement of the '995 patent; and/or contribution to the infringement by others of the '995 patent.

182. Upon information and belief, DRL has acted with full knowledge of the '995 patent and without a reasonable basis for believing that it would not be liable for infringement of the '995 patent; active inducement of infringement of the '995 patent; and/or contribution to the infringement by others of the '995 patent.

183. Plaintiff will be substantially and irreparably damaged by infringement of the '995 patent.

184. Unless DRL is enjoined from infringing the '995 patent, actively inducing infringement of the '995 patent, and contributing to the infringement by others of the '995 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XII—Declaratory Judgment of Infringement of the '995 Patent

185. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

186. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '995 patent, and/or the validity of the '995 patent.

187. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '995 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '995 patent, and that the claims of the '995 patent are not invalid.

Count XIII—Infringement of the RE '825 Patent

188. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

189. The RE '825 patent, entitled "4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Salt Crystal Forms" (attached as Exhibit G), was duly and legally issued on November 23, 2021.

190. The inventors named on the RE '825 patent are John Tomesch and Lawrence P. Wennogle.

191. Plaintiff is the owner and assignee of the RE '825 patent.

192. CAPLYTA® is covered by one or more claims of the RE '825 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

193. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under

the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the RE '825 patent.

194. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the RE '825 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the RE '825 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

195. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

196. Upon information and belief, DRL's ANDA Product and the use of DRL's ANDA Product are covered by one or more claims of the RE '825 patent, either literally or under the doctrine of equivalents.

197. As an example, claim 1 of the RE '825 patent recites:

> A 4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone toluenesulfonic acid addition salt crystal form, wherein said salt crystal form exhibits an X-ray powder diffraction pattern comprising at least two peaks selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°±0.2° 2θ.

198. Upon information and belief, DRL's ANDA Product contains a crystalline form of the compound recited in claim 1.

199. Upon information and belief, DRL's ANDA Product infringes one or more claims of the RE '825 patent, literally or under the doctrine of equivalents.

200. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the RE '825 patent was an act of infringement of the RE '825 patent under 35 U.S.C. § 271(e)(2)(A).

201. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

202. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the RE '825 patent.

203. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the RE '825 patent.

204. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the RE '825 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the RE '825 patent and specific intent to infringe that patent.

205. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the RE '825 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the RE '825 patent immediately and imminently upon approval of DRL's ANDA.

206. Notwithstanding DRL's knowledge of the claims of the RE '825 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the RE '825 patent.

207. The foregoing actions by DRL constitute and/or will constitute infringement of the RE '825 patent; active inducement of infringement of the RE '825 patent; and/or contribution to the infringement by others of the RE '825 patent.

208. Upon information and belief, DRL has acted with full knowledge of the RE '825 patent and without a reasonable basis for believing that it would not be liable for infringement of the RE '825 patent; active inducement of infringement of the RE '825 patent; and/or contribution to the infringement by others of the RE '825 patent.

209. Plaintiff will be substantially and irreparably damaged by infringement of the RE '825 patent.

210. Unless DRL is enjoined from infringing the RE '825 patent, actively inducing infringement of the RE '825 patent, and contributing to the infringement by others of the RE '825 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XIV—Declaratory Judgment of Infringement of the RE '825 Patent

211. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

212. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the RE '825 patent, and/or the validity of the RE '825 patent.

213. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the RE '825 patent, will infringe, induce infringement of, and contribute to the infringement by others of the RE '825 patent, and that the claims of the RE '825 patent are not invalid.

Count XV—Infringement of the '938 Patent

214. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

215. The '938 patent, entitled "Pharmaceutical Compositions Comprising ((6bR,10aS)-1-(4-fluorophenyl)-4-(3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)butan-1-one or Pharmaceutically Acceptable Salts Thereof" (attached as Exhibit H), was duly and legally issued on November 5, 2019.

216. The inventors named on the '938 patent are John Charles Tomesch, Peng Li, Wei Yao, Qiang Zhang, James David Beard, Andrew S. Thompson, Hua Cheng, and Lawrence P. Wennogle.

217. Plaintiff is the owner and assignee of the '938 patent.

218. CAPLYTA® is covered by one or more claims of the '938 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

219. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '938 patent.

220. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '938 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the

'938 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

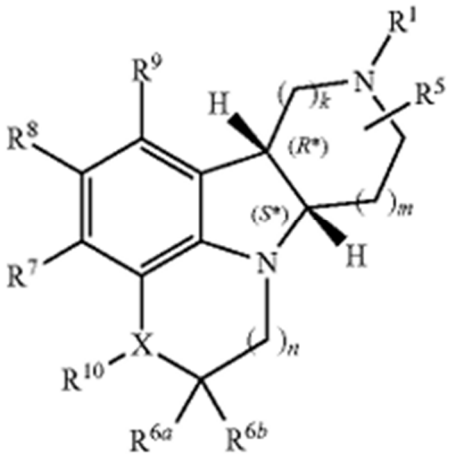
221. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

222. Upon information and belief, DRL's ANDA Product and the use of DRL's ANDA Product are covered by one or more claims of the '938 patent, either literally or under the doctrine of equivalents.

223. As an example, claim 1 of the '938 patent recites:

A pharmaceutical composition comprising toluenesulfonic acid and the compound of Formula 2J:

Formula 2J



or a pharmaceutically acceptable salt thereof,

wherein:

k is 1;

m is 1;

n is 1;

R^1 is 4-(4-fluorophenyl)-4-oxobutyl;

R^5 is H;

R^{6a} and R^{6b} are independently H;

R^7, R^8 and R^9 are independently H;

R^{10} is CH_3; and

X is —N—.

224. Upon information and belief, DRL's ANDA Product is a pharmaceutical composition comprising toluenesulfonic acid and the Formula 2J compound recited in claim 1.

225. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '938 patent, literally or under the doctrine of equivalents.

226. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '938 patent was an act of infringement of the '938 patent under 35 U.S.C. § 271(e)(2)(A).

227. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

228. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '938 patent.

229. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '938 patent.

230. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '938 patent when DRL's ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '938 patent and specific intent to infringe that patent.

231. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '938 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '938 patent immediately and imminently upon approval of DRL's ANDA.

232. Notwithstanding DRL's knowledge of the claims of the '938 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '938 patent.

233. The foregoing actions by DRL constitute and/or will constitute infringement of the '938 patent; active inducement of infringement of the '938 patent; and/or contribution to the infringement by others of the '938 patent.

234. Upon information and belief, DRL has acted with full knowledge of the '938 patent and without a reasonable basis for believing that it would not be liable for infringement of the '938 patent; active inducement of infringement of the '938 patent; and/or contribution to the infringement by others of the '938 patent.

235. Plaintiff will be substantially and irreparably damaged by infringement of the '938 patent.

236. Unless DRL is enjoined from infringing the '938 patent, actively inducing infringement of the '938 patent, and contributing to the infringement by others of the '938 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XVI—Declaratory Judgment of Infringement of the '938 Patent

237. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

238. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '938 patent, and/or the validity of the '938 patent.

239. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '938 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '938 patent, and that the claims of the '938 patent are not invalid.

Count XVII—Infringement of the '227 Patent

240. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

241. The '227 patent, entitled "Method for the Treatment of Residual Symptoms of Schizophrenia" (attached as Exhibit I), was duly and legally issued on May 1, 2018.

242. The inventors named on the '227 patent are Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle.

243. Plaintiff is the owner and assignee of the '227 patent.

244. CAPLYTA® is covered by one or more claims of the '227 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

245. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '227 patent.

246. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '227 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '227 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

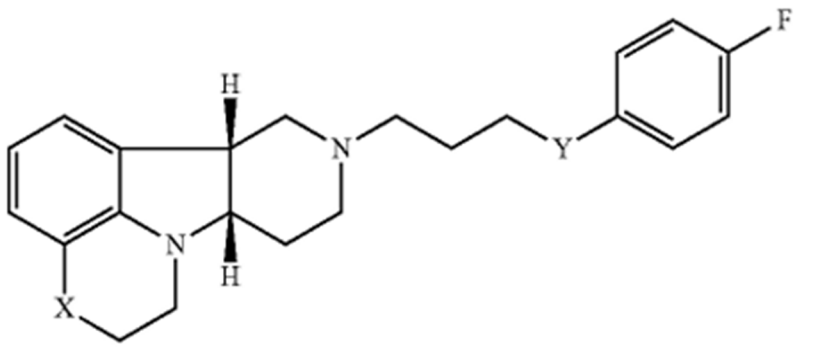
247. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

248. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling for that product would infringe one or more claims of the '227 patent.

249. As an example, claim 1 of the '227 patent recites:

> A method for the treatment of residual symptoms of schizophrenia as defined in the Positive and Negative Syndrome Scale (PANSS) for Schizophrenia, comprising administering to a patient in need thereof, after treatment of acute symptoms of schizophrenia with an antipsychotic agent, an effective amount of a compound of Formula I:

Formula I



wherein:

X is —O—, —NH— or —N(CH_3)—;

Y is —O—, —C(R_2)(OH)—, —C(R_3)(OR_1) or —C(O)—; and

R_1 is —C_{1-6} alkyl or —C(O)—C_{1-21} alkyl, optionally saturated or unsaturated and optionally substituted with one or more hydroxyl or C_{1-22} alkoxy groups wherein such compound hydrolyzes to form the residue of a natural or unnatural, saturated or unsaturated fatty acid;

R_2 is H or —C_{1-6} alkyl; and

R_3 is H or —C_{1-6} alkyl;

in free or pharmaceutically acceptable salt form;

wherein the patient significantly improves on the Prosocial PANSS Factor change from baseline.

250. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed label would involve treating residual symptoms of schizophrenia after treatment of acute symptoms of schizophrenia with an antipsychotic agent, including by administering to the patient in need thereof an effective amount of the compound recited in claim 1.

251. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '227 patent, literally or under the doctrine of equivalents.

252. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '227 patent was an act of infringement of the '227 patent under 35 U.S.C. § 271(e)(2)(A).

253. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

254. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '227 patent.

255. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '227 patent.

256. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '227 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '227 patent and specific intent to infringe that patent.

257. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '227 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '227 patent immediately and imminently upon approval of DRL's ANDA.

258. Notwithstanding DRL's knowledge of the claims of the '227 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '227 patent.

259. The foregoing actions by DRL constitute and/or will constitute infringement of the '227 patent; active inducement of infringement of the '227 patent; and/or contribution to the infringement by others of the '227 patent.

260. Upon information and belief, DRL has acted with full knowledge of the '227 patent and without a reasonable basis for believing that it would not be liable for infringement of the '227 patent; active inducement of infringement of the '227 patent; and/or contribution to the infringement by others of the '227 patent.

261. Plaintiff will be substantially and irreparably damaged by infringement of the '227 patent.

262. Unless DRL is enjoined from infringing the '227 patent, actively inducing infringement of the '227 patent, and contributing to the infringement by others of the '227 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XVIII—Declaratory Judgment of Infringement of the '227 Patent

263. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

264. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '227 patent, and/or the validity of the '227 patent.

265. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '227 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '227 patent, and that the claims of the '227 patent are not invalid.

Count XIX—Infringement of the '009 Patent

266. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

267. The '009 patent, entitled "Methods of Treating Schizophrenia and Depression" (attached as Exhibit J), was duly and legally issued on March 30, 2021.

268. The inventors named on the '009 patent are Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle.

269. Plaintiff is the owner and assignee of the '009 patent.

270. CAPLYTA® is covered by one or more claims of the '009 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

271. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '009 patent.

272. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '009 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '009 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

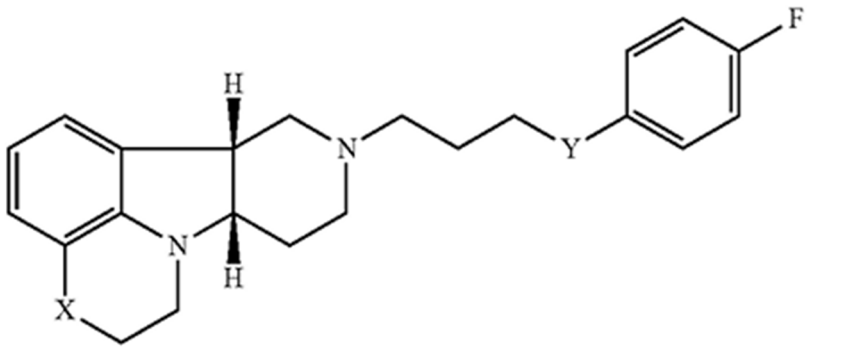
273. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

274. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling for that product would infringe one or more claims of the '009 patent.

275. As an example, claim 1 of the '009 patent recites:

A method for the treatment of the negative symptoms of schizophrenia comprising administering to a schizophrenic patient in need thereof an effective amount of a Compound of Formula I:

Formula I



wherein:

X is —N(CH_3)— and Y is —C(O)—;

in free or pharmaceutically acceptable salt form,

wherein the effective amount of the Compound of Formula I is 40 mg to 60 mg per day, measured as the weight of the corresponding free base form of the Compound.

276. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed label would involve treating negative symptoms of schizophrenia, including by administering to the patient in need thereof 40 mg to 60 mg (measured as the free base) per day of a Formula I compound in free or pharmaceutically acceptable salt form, as recited in claim 1.

277. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '009 patent, literally or under the doctrine of equivalents.

278. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's

ANDA Product before the expiration of the '009 patent was an act of infringement of the '009 patent under 35 U.S.C. § 271(e)(2)(A).

279. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

280. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '009 patent.

281. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '009 patent.

282. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '009 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '009 patent and specific intent to infringe that patent.

283. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '009 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '009 patent immediately and imminently upon approval of DRL's ANDA.

284. Notwithstanding DRL's knowledge of the claims of the '009 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's

ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '009 patent.

285. The foregoing actions by DRL constitute and/or will constitute infringement of the '009 patent; active inducement of infringement of the '009 patent; and/or contribution to the infringement by others of the '009 patent.

286. Upon information and belief, DRL has acted with full knowledge of the '009 patent and without a reasonable basis for believing that it would not be liable for infringement of the '009 patent; active inducement of infringement of the '009 patent; and/or contribution to the infringement by others of the '009 patent.

287. Plaintiff will be substantially and irreparably damaged by infringement of the '009 patent.

288. Unless DRL is enjoined from infringing the '009 patent, actively inducing infringement of the '009 patent, and contributing to the infringement by others of the '009 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XX—Declaratory Judgment of Infringement of the '009 Patent

289. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

290. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '009 patent, and/or the validity of the '009 patent.

291. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '009 patent, will infringe, induce

infringement of, and contribute to the infringement by others of the '009 patent, and that the claims of the '009 patent are not invalid.

Count XXI—Infringement of the '951 Patent

292. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

293. The '951 patent, entitled "Methods of Treating Bipolar Disorder" (attached as Exhibit K), was duly and legally issued on June 8, 2021.

294. The inventors named on the '951 patent are Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle.

295. Plaintiff is the owner and assignee of the '951 patent.

296. CAPLYTA® is covered by one or more claims of the '951 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

297. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '951 patent.

298. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '951 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '951 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

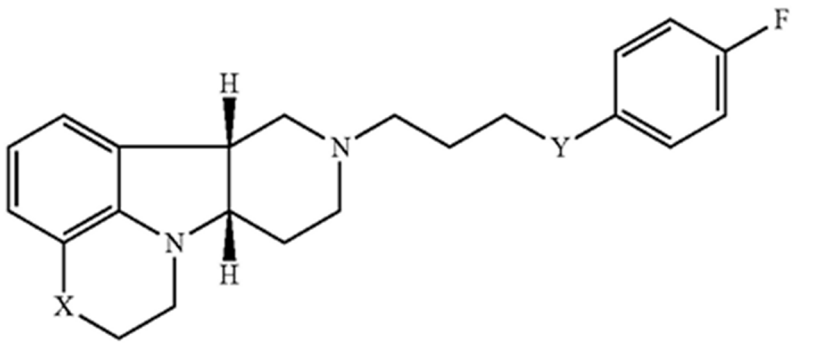
299. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

300. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling for that product would infringe one or more claims of the '951 patent.

301. As an example, claim 1 of the '951 patent recites:

> A method for the treatment of bipolar disorder I and/or bipolar II disorder comprising administering to a patient in need thereof an effective amount of a Compound of Formula I:

Formula I



> wherein:
>
> X is —N(CH_3)— and Y is —C(O)—;
>
> in free or pharmaceutically acceptable salt form, wherein said Compound is not used in combination with another antipsychotic agent.

302. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed label would involve treating bipolar disorder I and/or bipolar II disorder, including by administering to the patient in need thereof an effective amount of a Formula I compound in free or pharmaceutically acceptable salt form and not in combination with another antipsychotic agent.

303. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '951 patent, literally or under the doctrine of equivalents.

304. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's

ANDA Product before the expiration of the '951 patent was an act of infringement of the '951 patent under 35 U.S.C. § 271(e)(2)(A).

305. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

306. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '951 patent.

307. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '951 patent.

308. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '951 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '951 patent and specific intent to infringe that patent.

309. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '951 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '951 patent immediately and imminently upon approval of DRL's ANDA.

310. Notwithstanding DRL's knowledge of the claims of the '951 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's

ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '951 patent.

311. The foregoing actions by DRL constitute and/or will constitute infringement of the '951 patent; active inducement of infringement of the '951 patent; and/or contribution to the infringement by others of the '951 patent.

312. Upon information and belief, DRL has acted with full knowledge of the '951 patent and without a reasonable basis for believing that it would not be liable for infringement of the '951 patent; active inducement of infringement of the '951 patent; and/or contribution to the infringement by others of the '951 patent.

313. Plaintiff will be substantially and irreparably damaged by infringement of the '951 patent.

314. Unless DRL is enjoined from infringing the '951 patent, actively inducing infringement of the '951 patent, and contributing to the infringement by others of the '951 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XXII—Declaratory Judgment of Infringement of the '951 Patent

315. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

316. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '951 patent, and/or the validity of the '951 patent.

317. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '951 patent, will infringe, induce

infringement of, and contribute to the infringement by others of the ’951 patent, and that the claims of the ’951 patent are not invalid.

Count XXIII—Infringement of the ’345 Patent

318. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

319. The ’345 patent, entitled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate” (attached as Exhibit L), was duly and legally issued on June 30, 2020.

320. The inventors named on the ’345 patent are Peng Li and Robert Davis.

321. Plaintiff is the owner and assignee of the ’345 patent.

322. CAPLYTA® is covered by one or more claims of the ’345 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

323. In DRL’s Notice Letter, DRL notified Plaintiff of the submission of DRL’s ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL’s ANDA Product prior to the expiration of the Patents-in-Suit, including the ’345 patent.

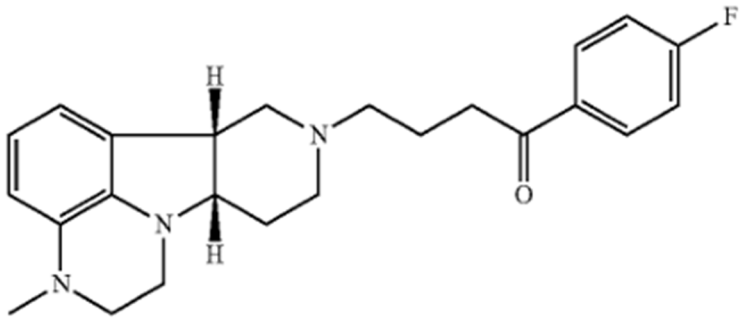
324. In DRL’s Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the ’345 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the ’345 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL’s ANDA Product.

325. According to DRL’s Notice Letter, DRL’s ANDA Product contains lumateperone.

326. Upon information and belief, DRL’s ANDA Product and the use of DRL’s ANDA Product are covered by one or more claims of the ’345 patent, either literally or under the doctrine of equivalents.

327. As an example, claim 1 of the '345 patent recites:

> A pharmaceutical capsule for oral administration, comprising lumateperone:



> in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and
>
> wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule.

328. Upon information and belief, DRL's ANDA Product is a pharmaceutical capsule for oral administration comprising lumateperone mono-tosylate in solid crystal form in a blend with the specific excipients in the specific amounts recited in claim 1.

329. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '345 patent, literally or under the doctrine of equivalents.

330. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's

ANDA Product before the expiration of the '345 patent was an act of infringement of the '345 patent under 35 U.S.C. § 271(e)(2)(A).

331. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

332. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '345 patent.

333. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '345 patent.

334. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '345 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '345 patent and specific intent to infringe that patent.

335. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '345 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '345 patent immediately and imminently upon approval of DRL's ANDA.

336. Notwithstanding DRL's knowledge of the claims of the '345 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's

ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '345 patent.

337. The foregoing actions by DRL constitute and/or will constitute infringement of the '345 patent; active inducement of infringement of the '345 patent; and/or contribution to the infringement by others of the '345 patent.

338. Upon information and belief, DRL has acted with full knowledge of the '345 patent and without a reasonable basis for believing that it would not be liable for infringement of the '345 patent; active inducement of infringement of the '345 patent; and/or contribution to the infringement by others of the '345 patent.

339. Plaintiff will be substantially and irreparably damaged by infringement of the '345 patent.

340. Unless DRL is enjoined from infringing the '345 patent, actively inducing infringement of the '345 patent, and contributing to the infringement by others of the '345 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XXIV—Declaratory Judgment of Infringement of the '345 Patent

341. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

342. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '345 patent, and/or the validity of the '345 patent.

343. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '345 patent, will infringe, induce

infringement of, and contribute to the infringement by others of the ’345 patent, and that the claims of the ’345 patent are not invalid.

Count XXV—Infringement of the ’084 Patent

344. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

345. The ’084 patent, entitled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate” (attached as Exhibit M), was duly and legally issued on July 6, 2021.

346. The inventors named on the ’084 patent are Peng Li and Robert Davis.

347. Plaintiff is the owner and assignee of the ’084 patent.

348. CAPLYTA® is covered by one or more claims of the ’084 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

349. In DRL’s Notice Letter, DRL notified Plaintiff of the submission of DRL’s ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL’s ANDA Product prior to the expiration of the Patents-in-Suit, including the ’084 patent.

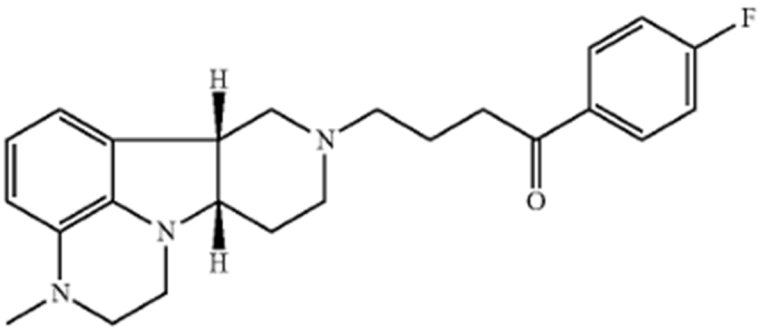
350. In DRL’s Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the ’084 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the ’084 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL’s ANDA Product.

351. According to DRL’s Notice Letter, DRL’s ANDA Product contains lumateperone.

352. Upon information and belief, DRL’s ANDA Product and the use of DRL’s ANDA Product are covered by one or more claims of the ’084 patent, either literally or under the doctrine of equivalents.

353. As an example, claim 1 of the '084 patent recites:

> A pharmaceutical capsule for oral administration, comprising lumateperone:



> in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and
>
> wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule,
>
> wherein the capsule comprises the lumateperone mono-tosylate in an amount equivalent to 0.01 to 30 mg of lumateperone free base.

354. Upon information and belief, DRL's ANDA Product is a pharmaceutical capsule for oral administration comprising 0.01 to 30 mg of lumateperone mono-tosylate in solid crystal form (measured as the free base) and the specific excipients in the specific amounts recited in claim 1.

355. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '084 patent, literally or under the doctrine of equivalents.

356. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '084 patent was an act of infringement of the '084 patent under 35 U.S.C. § 271(e)(2)(A).

357. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

358. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '084 patent.

359. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '084 patent.

360. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '084 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '084 patent and specific intent to infringe that patent.

361. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '084 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '084 patent immediately and imminently upon approval of DRL's ANDA.

362. Notwithstanding DRL's knowledge of the claims of the '084 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '084 patent.

363. The foregoing actions by DRL constitute and/or will constitute infringement of the '084 patent; active inducement of infringement of the '084 patent; and/or contribution to the infringement by others of the '084 patent.

364. Upon information and belief, DRL has acted with full knowledge of the '084 patent and without a reasonable basis for believing that it would not be liable for infringement of the '084 patent; active inducement of infringement of the '084 patent; and/or contribution to the infringement by others of the '084 patent.

365. Plaintiff will be substantially and irreparably damaged by infringement of the '084 patent.

366. Unless DRL is enjoined from infringing the '084 patent, actively inducing infringement of the '084 patent, and contributing to the infringement by others of the '084 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XXVI—Declaratory Judgment of Infringement of the '084 Patent

367. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

368. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '084 patent, and/or the validity of the '084 patent.

369. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug

product that is covered by or whose use is covered by the '084 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '084 patent, and that the claims of the '084 patent are not invalid.

Count XXVII—Infringement of the '842 Patent

370. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

371. The '842 patent, entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit N), was duly and legally issued on July 4, 2023.

372. The inventors named on the '842 patent are Peng Li and Robert Davis.

373. Plaintiff is the owner and assignee of the '842 patent.

374. CAPLYTA® is covered by one or more claims of the '842 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

375. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '842 patent.

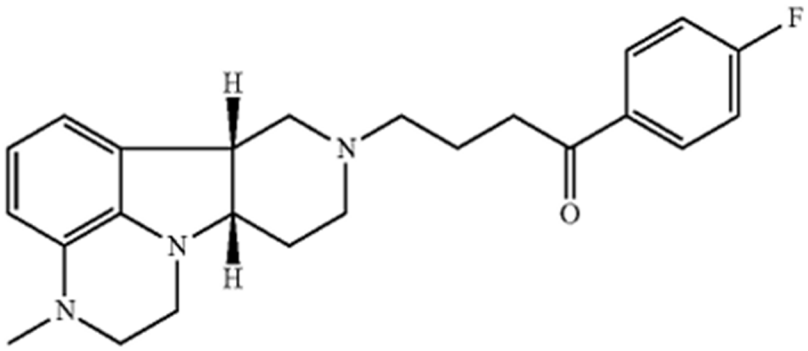
376. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '842 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '842 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

377. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

378. Upon information and belief, DRL's ANDA Product and the use of DRL's ANDA Product are covered by one or more claims of the '842 patent, either literally or under the doctrine of equivalents.

379. As an example, claim 1 of the '842 patent recites:

> A pharmaceutical capsule for oral administration, comprising lumateperone:



> in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and
>
> wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule, and
>
> wherein a single capsule dissolves in 500 mL of 0.1N aqueous hydrochloric acid to the extent of at least 85% after 15 minutes, and/or to the extent of at least 92% after 30 minutes, and/or to the extent of at least 94% after 45 minutes.

380. Upon information and belief, DRL's ANDA Product is a pharmaceutical capsule for oral administration comprising lumateperone mono-tosylate in solid crystal form and the specific excipients in the specific amounts recited in claim 1 and possessing the specific dissolution profile recited in claim 1.

381. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '842 patent, literally or under the doctrine of equivalents.

382. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '842 patent was an act of infringement of the '842 patent under 35 U.S.C. § 271(e)(2)(A).

383. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

384. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '842 patent.

385. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '842 patent.

386. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '842 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '842 patent and specific intent to infringe that patent.

387. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '842 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '842 patent immediately and imminently upon approval of DRL's ANDA.

388. Notwithstanding DRL's knowledge of the claims of the '842 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '842 patent.

389. The foregoing actions by DRL constitute and/or will constitute infringement of the '842 patent; active inducement of infringement of the '842 patent; and/or contribution to the infringement by others of the '842 patent.

390. Upon information and belief, DRL has acted with full knowledge of the '842 patent and without a reasonable basis for believing that it would not be liable for infringement of the '842 patent; active inducement of infringement of the '842 patent; and/or contribution to the infringement by others of the '842 patent.

391. Plaintiff will be substantially and irreparably damaged by infringement of the '842 patent.

392. Unless DRL is enjoined from infringing the '842 patent, actively inducing infringement of the '842 patent, and contributing to the infringement by others of the '842 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XXVIII—Declaratory Judgment of Infringement of the '842 Patent

393. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

394. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '842 patent, and/or the validity of the '842 patent.

395. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '842 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '842 patent, and that the claims of the '842 patent are not invalid.

Count XXIX—Infringement of the '348 Patent

396. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

397. The '348 patent, entitled "Methods of Treatment Using Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit O), was duly and legally issued on November 7, 2023.

398. The inventors named on the '348 patent are Peng Li and Robert Davis.

399. Plaintiff is the owner and assignee of the '348 patent.

400. CAPLYTA® is covered by one or more claims of the '348 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

401. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '348 patent.

402. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '348 patent. Upon information and belief,

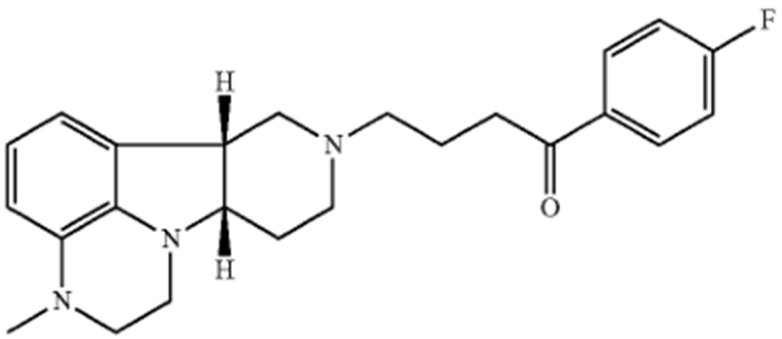
DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '348 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

403. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

404. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling for that product would infringe one or more claims of the '348 patent.

405. As an example, claim 1 of the '348 patent recites:

> A method for the treatment of a disease or disorder involving or mediated by the 5-HT_{2A} receptor, serotonin transporter (SERT), and/or dopamine D1/D2 receptor signaling pathways, comprising administering to a patient in need thereof a pharmaceutical capsule for oral administration, comprising lumateperone:



> in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and
>
> wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium,

0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule,

wherein the capsule comprises the lumateperone mono-tosylate in an amount equivalent to 0.01 to 30 mg or 35 to 45 mg of lumateperone free base.

406. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed label would involve treating a disease or disorder involving or mediated by the 5-HT_{2A} receptor, serotonin transporter (SERT), and/or dopamine D1/D2 receptor signaling pathways, including by administering to the patient in need thereof a pharmaceutical capsule for oral administration comprising 0.01 to 30 mg or 35 to 45 mg of lumateperone mono-tosylate in solid crystal form (measured as the free base) and the specific excipients in the specific amounts recited in claim 1.

407. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '348 patent, literally or under the doctrine of equivalents.

408. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '348 patent was an act of infringement of the '348 patent under 35 U.S.C. § 271(e)(2)(A).

409. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

410. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '348 patent.

411. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '348 patent.

412. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '348 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '348 patent and specific intent to infringe that patent.

413. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '348 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '348 patent immediately and imminently upon approval of DRL's ANDA.

414. Notwithstanding DRL's knowledge of the claims of the '348 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '348 patent.

415. The foregoing actions by DRL constitute and/or will constitute infringement of the '348 patent; active inducement of infringement of the '348 patent; and/or contribution to the infringement by others of the '348 patent.

416. Upon information and belief, DRL has acted with full knowledge of the '348 patent and without a reasonable basis for believing that it would not be liable for infringement of the '348 patent; active inducement of infringement of the '348 patent; and/or contribution to the infringement by others of the '348 patent.

417. Plaintiff will be substantially and irreparably damaged by infringement of the '348 patent.

418. Unless DRL is enjoined from infringing the '348 patent, actively inducing infringement of the '348 patent, and contributing to the infringement by others of the '348 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XXX—Declaratory Judgment of Infringement of the '348 Patent

419. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

420. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '348 patent, and/or the validity of the '348 patent.

421. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '348 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '348 patent, and that the claims of the '348 patent are not invalid.

Count XXXI—Infringement of the '419 Patent

422. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

423. The '419 patent, entitled "4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1h-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)-1-(4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1h-pyrido[3′4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)phenyl)butan-1-one for Treating Conditions of the Central Nervous System and Cardiac Disorders" (attached as Exhibit P), was duly and legally issued on September 12, 2023.

424. The inventors named on the '419 patent are Peng Li, Robert E. Davis, and Kimberly Vanover.

425. Plaintiff is the owner and assignee of the '419 patent.

426. CAPLYTA® is covered by one or more claims of the '419 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

427. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '419 patent.

428. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '419 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '419 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

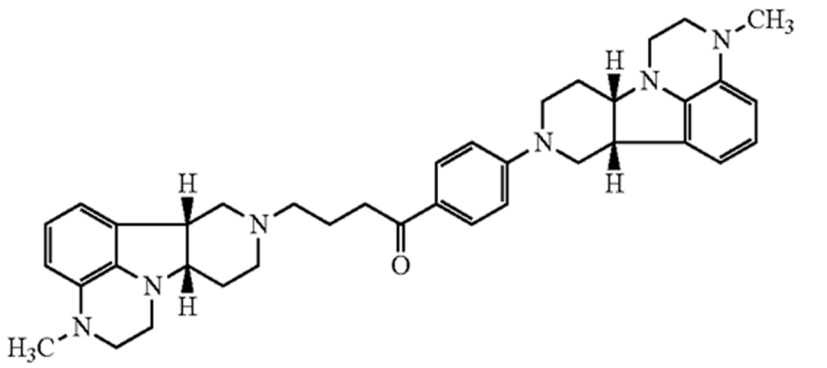
429. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

430. Upon information and belief, DRL's ANDA Product and the use of DRL's ANDA Product are covered by one or more claims of the '419 patent, either literally or under the doctrine of equivalents.

431. As an example, claim 1 of the '419 patent recites:

A compound of Formula I:

Formula I



in free base or pharmaceutically acceptable salt form.

432. Upon information and belief, DRL's ANDA Product contains a Formula I compound in free or pharmaceutically acceptable salt form, as recited in claim 1.

433. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '419 patent, literally or under the doctrine of equivalents.

434. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '419 patent was an act of infringement of the '419 patent under 35 U.S.C. § 271(e)(2)(A).

435. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

436. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '419 patent.

437. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '419 patent.

438. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '419 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '419 patent and specific intent to infringe that patent.

439. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '419 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '419 patent immediately and imminently upon approval of DRL's ANDA.

440. Notwithstanding DRL's knowledge of the claims of the '419 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '419 patent.

441. The foregoing actions by DRL constitute and/or will constitute infringement of the '419 patent; active inducement of infringement of the '419 patent; and/or contribution to the infringement by others of the '419 patent.

442. Upon information and belief, DRL has acted with full knowledge of the '419 patent and without a reasonable basis for believing that it would not be liable for infringement of the '419 patent; active inducement of infringement of the '419 patent; and/or contribution to the infringement by others of the '419 patent.

443. Plaintiff will be substantially and irreparably damaged by infringement of the '419 patent.

444. Unless DRL is enjoined from infringing the '419 patent, actively inducing infringement of the '419 patent, and contributing to the infringement by others of the '419 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XXXII—Declaratory Judgment of Infringement of the '419 Patent

445. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

446. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '419 patent, and/or the validity of the '419 patent.

447. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '419 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '419 patent, and that the claims of the '419 patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that the Patents-in-Suit have been infringed under 35 U.S.C. § 271(e)(2) by DRL's submission to the FDA of DRL's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of DRL's ANDA Product, or any other drug product that infringes or the use of which infringes the Patents-in-Suit, be not earlier than the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining DRL, and all persons acting in concert with DRL, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL's ANDA Product, or any other drug product covered by or whose use is covered by the Patents-in-Suit, prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product, or any other drug product covered by or whose use is covered by the Patents-in-Suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to infringement by others of said patents;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: March 28, 2024

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following actions:

- *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd. et al*, Civil Action No. 24-4264 (MAS/JBD); and
- *Intra-Cellular Therapies, Inc. v. Alkem Laboratories Ltd.*, Civil Action No. 24-4312.

Dated: March 28, 2024

By: *s/Liza M. Walsh*

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: March 28, 2024

By: *s/Liza M. Walsh*
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